

# Korean Bio-Pharma Industry Overview & Opportunities

**K**orea **I**nnovative **M**edicines **C**onsortium

2022.05.12.

**KIMC**   
(재)한국혁신의약품컨소시엄

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## Korea Innovative Medicines Consortium

1. Overview of Korean Bio-Pharma industry

2. Why Korea ?

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Korea is the fast mover in the bio-pharmaceutical industry, especially a big player within the biotechnology arena



**NO 1**

2021 Bloomberg  
Innovation Index



**3rd**

Largest pharma  
country in Asia,  
**\$20.4 billion** in 2020



**1,477**

Pipeline ownership of  
**7%** of global drug  
development



**34**

by MFDS

**7** approved by US FDA  
**7** approved by EMA



**4**

stem-cell therapy products  
developed globally



**790,000**

Annual production capacity in liters by 2023  
Korea is the world's 2<sup>nd</sup>-largest  
biopharmaceutical production base

(source : Bloomberg, KPBMA, KoriaBIO)

# 1. Korean Bio-Pharma industry/ Key Facts

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- Korea is transforming bio-pharma R&D and accelerating globalization

**\$ 20 B**

Biopharmaceutical market Size  
(2020)

**\$ 8.4 B**

Export Volume  
(2020)

**\$ 9.1 B**

Technology Transfer  
(2020)

- Korea has a high-profile for both private and public investment

**14.2 %**

Company R&D spending on revenues  
(2020)

**\$ 1.4 B**

Government R&D investment  
(2021)

**\$ 1.0 B**

Private VC investment  
(2021)

(source : KPBMA, 2022)

# 1. Korean Bio-Pharma industry/ Market Place

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- **Korea increasingly makes their presence in Asia ...“Your gateway for Asian market”**

- Total 254 global branches, where-in 119 branches set in Asia

## Plants

23



## Laboratories

26



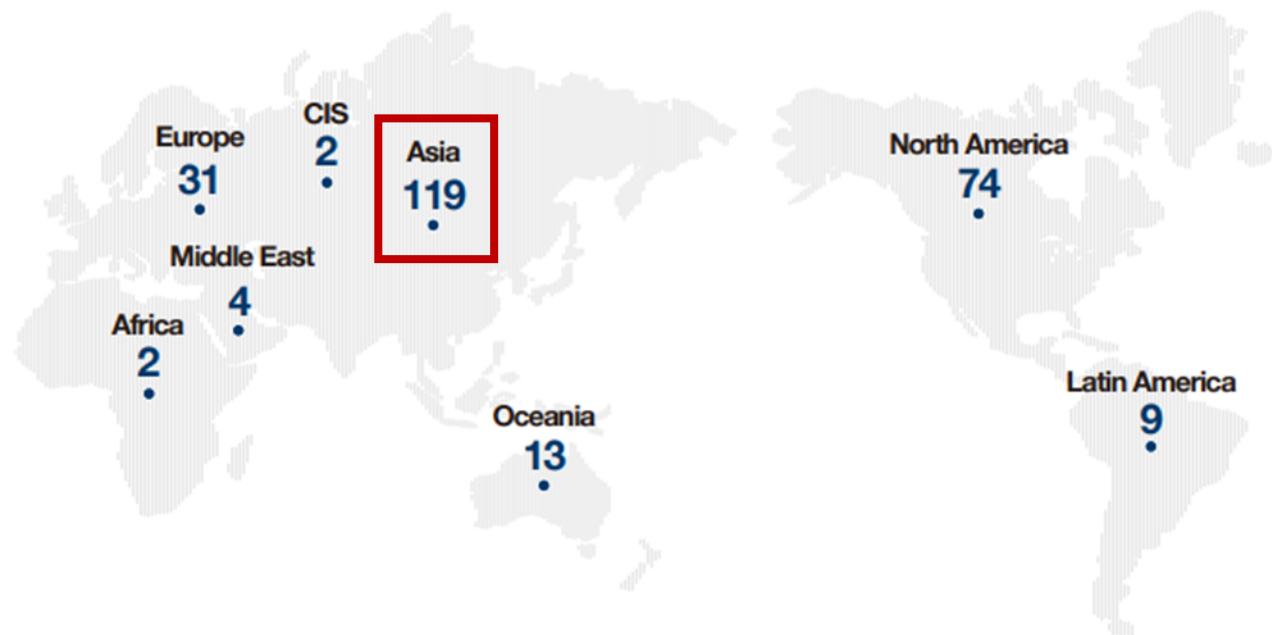
## Corporates

192



## Branch offices

13



(source : KPBMA, 2022)

## 2. Why Korea ?

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- R&D Capability
- Clinical Development Capability
- Manufacturing Capability

## 2-1. R&D : Strong Pipelines Dynamics

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- Advancing Technology Transfer performance, based on strong R&D investment

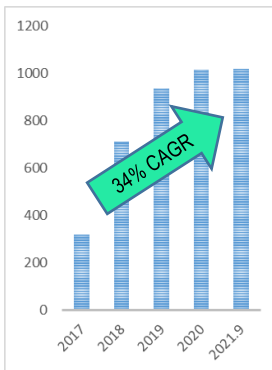
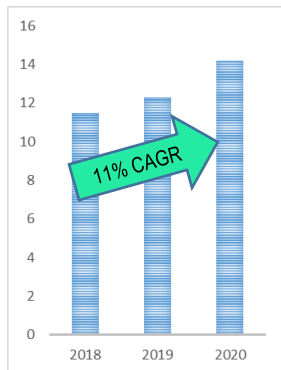
- Pipelines get quantum jump (CAGR 61%) & accelerating deal value (CAGR 54%)

### R&D Investment

- Keep going on high R&D investment

Biopharma Companies

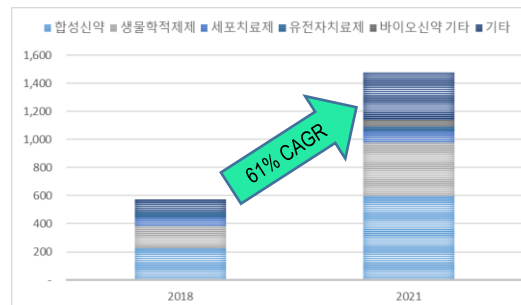
Venture Capital



### Pipelines

- 61 % quantum jump in the number of pipelines
- 1,477 of pipelines for new drug in 2021

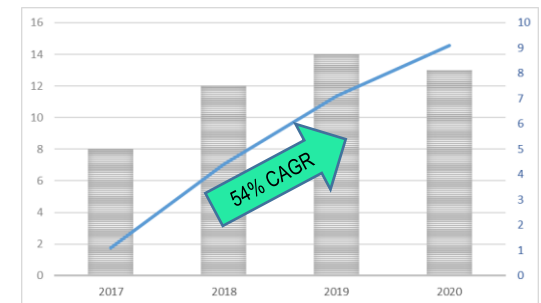
The number of pipelines



### Technology transfer

- Fast growing global deals
- Total Value of \$ 9 B, 13 cases in 2020

The number & deal value of tech transfer



(source : KPBMA, 2022)

## 2-2. Clinical Development capability

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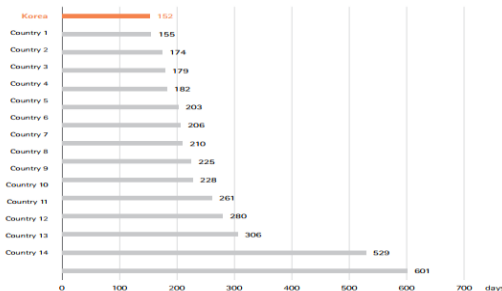
### • Excellent performance in both qualitative & quantitative perspectives

- **Seoul is one of world's top city** for global multicenter clinical trials (for the No. of SIT; KoNECT)

#### Faster Study

- MFDA approval 30 WDs
- IRB approval 3 Weeks
- SSU timelines 152 days

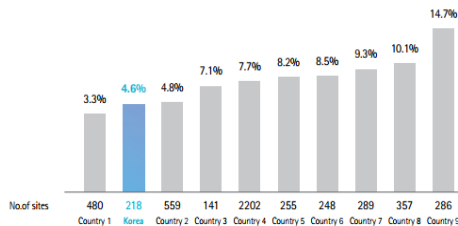
Protocol to Study Start-Up



#### High Quality

- 205 Clinical Trial Sites designated by government
- Non-recruiting sites rate 4.7%

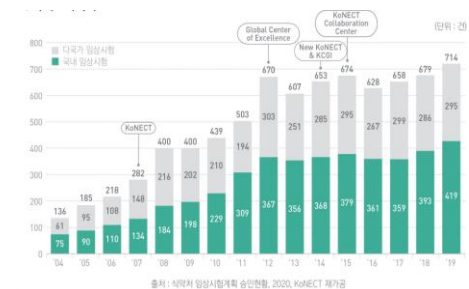
Proportion of Non-Recruiting Sites



#### Accumulated Experience

- 295 MRCTs in Korea
- Investing 596.3 billion won toward clinical R&D activities by global pharmaceutical companies

The number of INDs (MRCT/domestic)



출처 : 식약처 임상시험계획 승인현황, 2020, KoNECT 통계공  
 \* 국내 임상시험 : 제1차 등외 의약품 개발에 국한하여 실시되는 임상시험  
 \* 외국 임상시험 : 제1차 등외 의약품 개발하여 한국을 포함하여 2개국 이상에서 실시되는 임상시험

(source : KoNECT)



## 2-3. Manufacturing capability

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- Meeting bio-pharma quality on global high standards (PIC/S, ICH, EU White-list)

- Songdo ranks 1<sup>st</sup> in global biologics production capacity

### Meeting Global Quality Standards

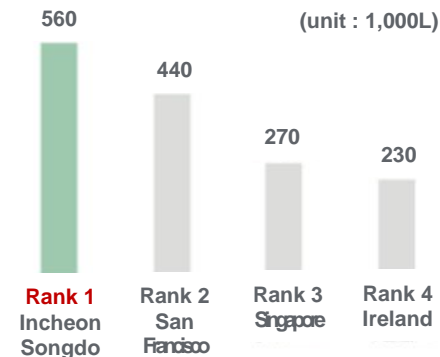
- 2014 Joining PIC/S
- 2016 Joining ICH
- 2019 Listed in EU White-list



### Huge manufacturing capacity of Biologics

- Global No.1 biopharma production capacity(by city, '20)

Global biologics production capacity (by city)



(source : KPBMA, KoBIA)

### 3. Collaboration Strategies with Korea

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- **R&BD** : You can strategize partnership from research, development to commercialization
- **Clinical Development** : You can leverage fast speed & high quality of clinical trials
- **Manufacturing** : You can collaborate with a high quality of CDMO

# 3-1. Collaboration in R&BD

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## • You can strategize partnership from research, development to commercialization

- Business cases collaborating with Korean / Global companies

### Sanofi – ABL Bio (ABL301, L/O)

- Deal Date : 2022-01-11
  - Deal Value : \$ 1.06 B
  - Licensed out WW development & commercialization rights
- <Pipeline Information>
- Indication : Parkinson's disease
  - Technology : Monoclonal antibody

### J&J – Yuhan (Lazertinib, L/O)

- Deal Data : 2018-11-06
  - Deal Valuate : \$ 1.26 B
  - Licensed out and agreed WW collaboration
  - **Development collaboration for global clinical trials – lead mono therapy by Yuhan and combination therapy by J&J**
- <Pipeline Information>
- Indication : NSCLC
  - Technology : Small molecule chemistry

### Hanmi – RAPT therapeutics (FLX475, L/I)

- Deal Date : 2019-12-03
  - Deal Value : \$ 118 M
  - **Licensed in and collaboration agreement for product development in Asia**
- <Pipeline Information>
- Indication : Solid tumour
  - Technology : Small molecule chemistry

(source : Evaluate Pharma)

## 3-2. Collaboration in Clinical Development

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- **You can leverage fast speed & high quality of clinical trials**

- Business cases collaborating with Korean sites & Global companies

### Pfizer

- Select 4 hospitals(SNUH, Severance Hospital, AMC, and Samsung Seoul Hospital) as institutions that can carry out 50% of Pfizer's P2
- Classified Korea as a core country for new drug R&D
- '21 IND in Korea : Total 12 cases (2 of P1, 3 of P2, 5 of P3)

### Sanofi

- Conclude preferential negotiations for new drug clinical trials with 4 hospitals(SNUH, Severance Hospital, AMC, and Samsung Seoul Hospital)
- established the 'Premier Network', a comprehensive clinical research
- '21 IND in Korea : Total 17 cases (4 of P1, 7 of P2, 6 of P3)

### Novartis

- Ranked 1<sup>st</sup> global pharmaceutical companies in the number of IND in Korea for 6 years from 2013 to 2018
- Signed a mutual business agreement with The Catholic Big Data Integration Center and the Catholic Big Data Integration Center
- '21 IND in Korea : Total 27 cases (5 of P1, 3 of P2, 15 of P3)

(source : KRPIA, MFDS)

## 3-3. Collaboration in Development & Manufacturing

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- You can find a high quality of CDMO

- Business cases collaborating with Korean / Global companies

### Yuhan

- Small molecule CDMO, contract with such as Gilead for hepatitis C treatment & HIV treatment APIs

### Samsung Biologics

- Biosimilar/biologic CDMO, contract such as for GSK drug for autoimmune disease lupus (\$231M, '20)

### ST pharm

- CDMO, world 's 2nd largest oligonucleotide production

### SK Bioscience

- Vaccine CDMO, contract such as AstraZeneca & Novavax - contract for raw material manufacturing and filling for COVID-19 vaccine

(source : DART & article)

- Your partner for advancing R&BD
- Your partner for accelerating Clinical Development
- Your partner for high quality CDMO

**Korea is your gateway for Asia & Global market.**

Please feel free to contact for strategic collaboration with Korea.

Ask KIMCo : [kimco@kimc.or.kr](mailto:kimco@kimc.or.kr)